March 12, 2018

Exactech, Inc.
Shing Jen Tai
Senior Regulatory Specialist
2320 NW 66th Court
Gainesville, Florida 32653

Re: K173583
Trade/Device Name: Exactech® Novation® and AcuMatch® E-HXL Acetabular Liners
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: OQI, LZO, MEH
Dated: February 7, 2018
Received: February 8, 2018

Dear Shing Jen Tai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173583

Device Name

Exactech® Novation® and AcuMatch® E-HXL Acetabular Liners

Indications for Use *(Describe)*

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

- Cemented femoral stems and cemented acetabular cups are intended for cemented fixation only.
- Press-fit femoral stems and acetabular cups are intended for press-fit fixation.
- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Exactech® Novation® and AcuMatch® E-HXL Acetabular Liners
Traditional 510(k) - 510(k) Summary

Company: Exactech®, Inc
2320 NW 66th Court
Gainesville, FL 32653

Date: March 12, 2018

Contact Person: Shing Jen Tai, PhD
Sr. Regulatory Affairs Specialist

Phone: (352) 327-4638
Fax: (352) 378-2617

Proprietary Name: Exactech® Novation® and AcuMatch® E-HXL Acetabular Liners

Common Name: Total Hip Prosthesis Acetabular Component

Classification Name: 21 CFR 888.3353, Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented or Nonporous Uncemented Prosthesis

Class II

Product Code: OQI, LZO, MEH

Legally Marketed Device to Which Substantial Equivalence Is Claimed:

- Exatech® AcuMatch® A-Series Connexion GXL Enhanced UHMWPE Acetabular Liner (K051556)
- Exactech Novation® Crown Cup® and Liners (K070479)
- Exactech Novation®Crown Cup® and Liners (K100269)
- Exactech Novation® Crown Cup® GXL UHMWPE Liner (K121392)
- Corin Trinity Acetabular System ECIMA Liners (K111481)

Reference Devices

- Biomet E1 Polyethylene Liners (K050327)

Device Description

Exactech Novation and AcuMatch E-HXL Acetabular Liners are intended for use in total hip replacement as an interface between acetabular shells and femoral heads. Both Novation E-HXL Acetabular Liners and AcuMatch E-HXL Acetabular Liners are manufactured from Ultra-High Molecular Weight Polyethylene containing vitamin E (alpha tocopherol). The Novation E-HXL Acetabular Liners are available in five

configurations (neutral, lipped, anterior lipped, +5mm lateralized, and 10 deg. face changing) with inner diameter ranging between 22mm and 40mm. The AcuMatch E-HXL Acetabular Liners are available in four configurations (0 deg., 15 deg., ext coverage, and +5mm lateralized) with inner diameter ranging between 28mm and 36mm. The overall design goals of the proposed Exactech Novation and AcuMatch E-HXL Acetabular Liners are to improve wear performance and provide oxidative stability in comparison to the predicate Exactech Novation and AcuMatch GXL Acetabular Liners.

Indications for Use
All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

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- Press-fit femoral stems and acetabular cups are intended for press-fit fixation.
- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.

Summary of Technological Characteristics
The rationale for substantial equivalence is based on consideration of the following device use and characteristics:

- **Indications for Use.** The proposed Exactech Novation and AcuMatch E-HXL Acetabular Liners and the predicate devices have the same or similar indications for use.
- **Materials.** The proposed Exactech Novation and AcuMatch E-HXL Acetabular Liners and the predicate devices are composed of the same or similar biocompatible materials.
- **Design Features.** The proposed Exactech Novation and AcuMatch E-HXL Acetabular Liners and the predicate devices have the same or similar design features.
- **Dimensions.** The proposed Exactech Novation and AcuMatch E-HXL Acetabular Liners and the predicate devices are dimensionally equivalent or comparable.
- **Sterilization.** The proposed Exactech Novation and AcuMatch E-HXL Acetabular Liners and the predicate devices are provided sterile for single use only.

- **Performance Requirements.** The proposed Exactech Novation and AcuMatch E-HXL Acetabular Liners and the predicate devices conform to recognized performance standards for total hip replacement devices.

Non-Clinical Testing

The following material characterization, biocompatibility testing/analysis, wear analyses, mechanical testing, and engineering evaluation were performed to demonstrate that the Exactech Novation and AcuMatch E-HXL Acetabular Liners perform as intended and are substantially equivalent to the identified predicate devices:

- Material Characterization
- Biocompatibility Testing and Analysis
- Extractive Testing
- Standard and Aggressive Wear Analyses
- Impingement Testing
- Axial Push-Out Testing
- Torque Out Testing
- Offset Pull-Out Testing
- Range of Motion Analysis

Pyrogen testing was conducted in accordance with USP <161>, USP <85>, and ANSI/AAMI ST72 to ensure the proposed Novation and AcuMatch E-HXL Acetabular Liners meet recommended limits per FDA's *Guidance Document Submission and Review of Sterility Information in Premarket (510(k)) Submission for Devices Labeled as Sterile*.

Substantial Equivalence Conclusion

Based on consideration of indications for use, technological characteristics, biocompatibility of the proposed devices, and results of material characterization, wear analyses, mechanical testing, and engineering evaluation, it was concluded that the Exactech Novation and AcuMatch E-HXL Acetabular Liners demonstrate substantial equivalence to the referenced predicate devices.